Nguyet Phan
01/12/04 12:42 PM

To: NCIC HPV
cc:
Subject: Environmental Defense comments on Thiodiethylene bis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS# 41484-35-9)

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Nguyet Phan
ASRC Aerospace
OPPT Docket
EPA Docket Center

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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, richard.balcomb@cibasc.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Thiodiethylene bis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS# 41484-35-9)

(Submitted via Internet 1/12/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and richard.balcomb@cibasc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Thiodiethylene bis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS# 41484-35-9).

Ciba Specialty Chemicals has submitted Robust Summaries/Test Plan describing available data and testing needs for thiodiethylene bis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate), commonly known as Irganox 1035. Irganox 1035 is used as a thermal stabilizer in polyolefins and other polymers and as an antioxidant in both synthetic monomers and polymers. It has been approved by the US Food and Drug Administration for use in polymers, resins and adhesives employed in the food industry. This material is not readily biodegradable but appears to have low to negligible toxicity in all systems tested.

Ciba has submitted a concise Test Plan for Irganox 1035 that describes available studies of this chemical and includes a matrix indicating availability of data or proposed testing for each of the SIDS elements requested under the HPV Challenge. With the exception of developmental toxicity, all requested SIDS elements have been addressed by acceptable studies. Studies to address the developmental toxicity of Irganox 1035 are proposed. The only information lacking in the Test Plan that would be useful to include is a brief description of transport of Irganox 1035 from the site(s) of its production to Ciba's customers.

Data briefly described in the Test Plan are supported by Robust Summaries that are described in some detail. These summaries indicate that Irganox 1035 does not readily degrade in the environment, but toxicity to aquatic organisms is observed only at doses that exceed the solubility of this compound in water. Further, this material appears to be virtually nontoxic to mammals and nonmutagenic.

In summary, the Test Plan and Robust Summaries for Irganox 1035 are carefully prepared and, together with data from the proposed studies, are sufficient to meet the program requirements.

Thank you for this opportunity to comment.

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